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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,817	02/27/2004	John G. Babish	068911-0074	5656

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EXAMINER	
CARTER, KENDRA D	

ART UNIT	PAPER NUMBER
1617	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,817	BABISH ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 June 2009*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9 and 11-32* is/are pending in the application.

4a) Of the above claim(s) *16-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9 and 11-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/10/09;6/26/09*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 26, 2009 has been entered.

The Examiner acknowledges the applicant's remarks and arguments of June 26, 2009 made to the office action filed December 23, 2008. Claims 1-7, 9 and 11-32 are pending. Claim 1 is amended and claims 8 and 10 are cancelled. Claims 16-32 are withdrawn.

For the reasons in the previous office action and below, the Applicant's arguments of the 35 USC 103(a) rejection of claims 1-15 were found not persuasive.

Due to the amendment to the claims, the modified 35 USC 103(a) rejection and a new obvious double patenting rejection are made below. The Applicant's arguments are addressed below.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-7, 9 and 11-15 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/590,424 ('424) in view of Ramirez (US 2002/0102345 A1) in view of Chappel et al. (Food and chemical Toxicology, 1998, vol. 36, pp. 915-922).

This is a provisional obviousness-type double patenting rejection.

The application '424 teaches the same composition as the current application except for the compound and the methylxanthine being in an ant-inflammatory synergistic amount.

In regards to the use of the composition claimed in the present invention for the treatment of inflammation and the composition having "anti-inflammatory" synergistic amounts, the intended use does not get patentable weight. The reason for combining the prior art does not have to be the same as the Applicant. The claims are examined on the merits of a composition and not a method for treatment of inflammation.

Ramirez teaches a beverage composition (i.e. oral and inherently possess a pharmaceutically acceptable carrier; addresses claims 14 and 15) comprising beer (see page 2, paragraph 29, line 3 and claim 1) and caffeine (see page 6, paragraphs 85-91 and claim 13; addresses claim 1, 7 and 9). Once the base composition is provided, special ingredients may then be incorporated into the liquid in such quantities and relative proportions that help enhance the body's alertness and energy sensation (see page 6, paragraph 82).

Chappel et al. teaches that during the storage of hops, deterioration may occur with losses in bittering value, thus tetrahydroisohumulones are manufactured from alpha acids, such as those elected by the applicant, that are more stable and provide more

efficient bittering agent that can be added to beer late in the brewing process (see page 915, column 2, first full paragraph in its entirety).

To one of ordinary skill in the art at the time of the invention would have found it obvious to have methylxanthine and tetra-hydroisoalpha acids in synergistic amounts because Chappel et al. teach that tetrahydroisohumulones are manufactured from alpha acids, such as those elected by the applicant, that are more stable and provide more efficient bittering agent that can be added to beer late in the brewing process (see page 915, column 2, first full paragraph in its entirety). Thus, by adding tetra-hydroisoalpha acids to the beer composition of Ramierz, a more efficient and stable bittering agent is provided.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 9 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramirez (US 2002/0102345 A1) in view of Chappel et al. (Food and chemical Toxicology, 1998, vol. 36, pp. 915-922).

Ramirez teaches a beverage composition (i.e. oral and inherently possess a pharmaceutically acceptable carrier; addresses claims 14 and 15) comprising beer (see page 2, paragraph 29, line 3 and claim 1) and caffeine (see page 6, paragraphs 85-91 and claim 13; addresses claim 1, 7 and 9). Once the base composition is provided, special ingredients may then be incorporated into the liquid in such quantities and relative proportions that help enhance the body's alertness and energy sensation (see page 6, paragraph 82).

Ramierz does not teach tetra-hydroisoalpha acid either derived or not derived from hops as disclosed in claims 1-6, nor the amounts of the compound nor ratio to the methylxanthine as disclosed in claims 1, 9 and 11-13.

Chappel et al. teaches that during the storage of hops, deterioration may occur with losses in bittering value, thus tetrahydroisohumulones are manufactured from alpha acids, such as those elected by the applicant, that are more stable and provide more efficient bittering agent that can be added to beer late in the brewing process (see page 915, column 2, first full paragraph in its entirety).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the composition of Ramierz and tetra-hydroisoalpha acids as those disclosed in claims 1-6 because Chappel et al. teaches that these compounds are added to the brewing process of beer to provide a more stable and efficient bittering agent. Thus, in the brewing of the Ramierz beer, one skilled in the art would be motivated to add a more stable and efficient bittering agent in order to overcome the problem of the beer not having a true taste of the bitterness in beer.

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the composition of Ramierz in view of Chappel et al. and the amounts of the tetra-hydroisoalpha acid and methylxanthine as well as the ratio between the two compounds as disclosed in claims 1, 9 and 11-13 because one skilled in the art would be able to adjust the amounts of these compounds in order to provide the desired effect of bitterness (tetra-hydroalpha acid) and energy boost (methylxanthine; caffeine). Ramiez teaches that once the base composition is provided, special ingredients may then be incorporated into the liquid in such quantities and relative proportions that help enhance the body's alertness and energy sensation (see page 6, paragraph 82).

In regards to the use of the composition claimed for the treatment of inflammation and the composition having "anti-inflammatory" synergistic amounts, the intended use does not get patentable weight. The reason for combining the prior art does not have to

be the same as the Applicant. The claims are examined on the merits of a composition and not a method for treatment of inflammation.

In regards to methylxanthine and tetra-hydroisoalpha acids being in synergistic amounts, Ramierz in view of Chappel et al. teach a synergistic amounts because Chappel et al. teach that tetrahydroisohumulones are manufactured from alpha acids, such as those elected by the applicant, that are more stable and provide more efficient bittering agent that can be added to beer late in the brewing process (see page 915, column 2, first full paragraph in its entirety). Thus, by adding tetra-hydroisoalpha acids to the beer composition of Ramierz, a more efficient and stable bittering agent is provided.

Response to Arguments

Applicant's arguments filed June 26, 2009 have been fully considered but they are not persuasive.

The Applicant argues that when reduced isoalpha acids (e.g. tetra-hydroisoalpha acids) and methylzanthines (e.g. caffeine) are combined in certain amounts, they have syntergistic anti-inflammatory effects. Neither Ramierez nor Chappel et al. teach or suggest anti-inflammation, synergy or the ratio amounts in the amended claims.

The Examiner disagrees because the synergistic amounts are still not commenserate to scope. The claims encompass any methylxanthine and any reduced isoalpha acid, tetrahydroisoalpha acid, or hexa-hydroisoalpha acid at ratios were synergy was not shown. The specification demonstrates synergy with RIAA and curcumin in certain ratios (see page 44, table 5). For instance, RIAA alone has an IC50 of 0.81 but does not get better with the addition of curcumin. On the other hand curcumin alone has an IC50 of 1.4 and only gets better at a ratio of 3:2 (IC50 = 1.1) and 3:1 (IC50 = 1.3) of RIAA:Curcumin. Interestingly, RIAA alone in Table 7 has an IC50 of 1:3 and only gets better at a ratio of 1:1 (IC50 = 0.91), 2:3 (IC50 = 1) and 1:10 (IC50 = 1.2) of RIAA:Caffeine. On the other hand caffeine alone has an IC50 of 25 and at all ratios has a better IC50 value. Further, RIAA is defined as rho-iso-alpha acids (see paragraph 126), thus all of the specific compounds claimed in claim 1 are not those in which specifically demonstrated synergy in Tables 5 and 7. Therefore, synergy does not exist with all of the compound combinations and ratios of the current claims. Again, the Examiner would like to note that the anti-inflammatory effect and "anti-inflammatory" synergistic amounts of the composition do not get patentable weight in composition claims. The claims are only treated on the merits as related to a composition. The Examiner suggests amending the claims to the ratios with the specific compounds presented in Tables 5 and 7 that demonstrate synergy.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 7:30 am - 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/K. D. C./
Examiner, Art Unit 1617

/SREENI PADMANABHAN/
Supervisory Patent Examiner, Art Unit 1617